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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/779,457	01/07/1997	PAUL J. CARTER	P0986P2	5894

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EXAMINER	
BELYAVSKYI, MICHAIL A	

ART UNIT	PAPER NUMBER
1644	39

DATE MAILED: 05/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/779,457	CARTER ET AL.	
	Examiner	Art Unit	
	Michail A Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,11,12 and 22-29* is/are pending in the application.

4a) Of the above claim(s) *23 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,11,12,22 and 25-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02/20/03* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 2/26/03 (Paper No. 38), is acknowledged.

Claims 1-8, 11-12 and 22-29 are pending.

Claims 23 and 24 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

Claims 1-8, 11, 12, 22 and25-29 are under consideration in the instant application.

2. The amendment filed 2/26/03 (Paper No. 38), is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: on page 69, line 7, insertion of the description from the cited Levin et al. reference that is relevant to testing molecules such as agonist antibodies for their ability to modulate body weight. The amendatory material is considered a new matter because Applicant has not provided **affidavit or declaration** stating that said amendatory material consists of the same material incorporated by reference in the referencing application.

In view of the amendment, filed 2/26/03 (Paper No. 38), the following rejections remain:

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-8, 11-12, 22 and 25-29 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the same reasons set forth in the previous Office Action, Paper No: 37, mailed 9/10/02.

The attempt to incorporate subject matter into this application by reference Levin et al.,(Proc. Natl. Acad. Sci.USA 93:1726-1730, 1996) for the methods for screening for antibody which induces a statistically significant decrease in body weight and /or fat depot weight and/or food intake in an obese mammal, on page 69, lines 1-7 of the specification is improper because an application for a patent when filed may incorporate "essential material" by reference to (1) a United States patent or (2) an allowed U.S. application, subject to the conditions set in the MPEP 608.01(p).

Applicant's arguments, filed 9/25/00 (Paper No. 10), have been fully considered, but have not been found convincing.

Applicant asserts that the specification has been amended to add the description from the cited Levin et al. reference that is relevant to testing molecules such as agonist antibodies for their ability to modulate body weight.

As was stated in the previous Paper No: 37, mailed 9/10/02, " The amendment must be accompanied by an **affidavit or declaration** executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See In re Hawkins, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); In re Hawkins, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and In re Hawkins, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

It is noted that Applicant has not provided said affidavit or declaration.

5. Claims 1, 3-8, 11,12, 22 and 25-29 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for identifying an antibody which decreases body weight or fat-depot weight or food intake in obese *ob/ob* mice , does not reasonably provide enablement for a method for identifying an antibody which decreases body weight or fat-depot weight or food intake in any obese animal including human. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims essentially for the same reasons set forth in the previous Office Action, Paper No: 37, mailed 9/10/02.

Applicant's arguments, filed 9/25/00 (Paper No. 10), have been fully considered, but have not been found convincing.

Applicant asserted that: (i) the claims are directed to a method for identifying agonist antibodies with a particular property and are not directed to a particular antibody; (ii) one of the ordinary skill in the art will be able to produce agonist antibodies which specifically binds to the extracellular domain of a receptor having a WSX motif comprising the extracellular domain sequence within SEQ ID NO:2; (iii) agonist antibody can be selected that decrease body weight or fat-depot weight in any obese mammal ; (iv) one of ordinary skill in the art would not have any reason to believe that the claimed method coud not be performed with any obese animal.

Contrary to Applicant assertion, the issue raised in the previous Office Action was not about: (i) ability of one of the ordinary skill in the art to produce agonist antibodies which specifically binds to the extracellular domain of a receptor having a WSX motif comprising the extracellular domain sequence within SEQ ID NO:2 or (ii) any particular antibody.

As was stated in the Previous Office Action, the instant claims are directed to a method for identifying an antibody which decreases body weight or fat-depot weight or food intake in any obese animal including human. The data which is provided in the instant specification are based solely on administration of antibodies to ob/ob mice. However, one of skill in the art would not reasonably expect that a method for identifying an antibody which decreases body weight or fat-depot weight or food intake in the ob/ob mouse to be predictive for a method for identifying an antibody which decreases body weight or fat-depot weight or food intake in any obese animal including human. The ob/ob mouse is an animal which possesses a genetic mutation that leads to an obese phenotype that is realized at one month of age. Although the phenotype is similar in various obese animal, including human, the genetic alteration that causes the condition in mice has not been confirmed in humans in order to establish the predictability of the rodent model for humans. The working hypothesis for the ob/ob mouse is that there is a loss of a circulating satiety factor which would lead to reduction in weight and body fat if antibody to WSX or Ob/ leptin receptor are administered, and therefore, treatment of the obese. However, as no such genetic defect has been attributed to the obese condition in humans, one would not expect the same factor to be effective in humans to decrease body weight or fat-depot weight or food intake, absent evidence to the contrary. As confirmation of this scientific reasoning, researchers have found that except for the leptin-deficient obese mice (i.e. ob/ob mice), most obese mammals have elevated plasma concentrations of leptin and insulin and appear to be resistant to leptin-induced anorexia (see Woods et al. Science, 280: 1378-1383, 1998) and there is speculation that human obesity is due to reduced brain responsiveness to OB since most obese individuals have elevated serum levels of OB (see Campfield et al. Science, 280: 1383-1387, 1998).

6. The filing date of the instant claims is the filing date of the instant applications, i.e. 01/07/1997, as the previous priority applications 08/667,197 and 08/585,005 do not support the claimed limitations of the instant application, encompassing a method for identifying an antibody recited in claims 1-8, 11,12, 22 and25-29

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

8. Claims 1-8, 11, 12, 22 and 25-29 stand rejected under 35 U.S.C. 102(e) as being anticipated by Tartaglia et al. (US. Patent 5,972621) essentially for the same reasons set forth in the previous Office Action, Paper No: 37, mailed 9/10/02.

Applicant's arguments, filed 9/25/00 (Paper No. 10), have been fully considered, but have not been found convincing.

Applicant asserted that US Patent '621 fail to disclose a method for identifying antibodies that decrease body weight and that the passages pointed by the examiner only discuss antibody to ObR generally. However, Applicant acknowledge that US Patent '621 do list antibodies that specifically bind to human receptor ObR that is the same extracellular domain of the receptor having a WSX motif, as claimed in the instant application (see Applicant Response, Paper NO:10, page 9, in particular) .

Contrary to Applicant assertion, as was stated in the previous Office Action US Patent '621 teaches a method for identifying antibody which decrease body weight in animals, by specifically binding to extracellular domain of ObR(see entire document, Abstract , column 5, lines 44-60, column 6, lines 50-55 and column 8, lines 22-25 in particular). Moreover, even the title of the US Patent '621 read on "method of identifying compounds that modulate body weight using the OB receptor". The method of identifying antibody comprises producing antibody, testing and identifying antibody that have an ability to decrease body weight (see column 22-23 in particular). Applicant himself acknowledge that US Patent '621 teaches antibody as one of the compounds (see Applicant response, Paper NO:10, page 9, in particular). US Patent '621 teaches a method for identifying antibody which decrease body weight in obese animals, wherein the obese animal is *ob/ob* mice (column 2, lines 39-48 in particular). US Patent '621 teaches a method for identifying antibody which decrease body weight in obese animals, wherein said antibody specifically bind to human receptor ObR (see column 22, lines 43-45 in particular). US Patent '621 teaches that said antibody is monoclonal or fragment wherein said fragment is $F(ab')_2$ (column 22, lines 16-25 in particular), or human antibody, or humanized or antibody that also bind to a murine ObR receptor (column23, lines 12-24 in particular).

Claims 4-5 and 7-9 are included because both the reference method of identifying an antibody and the claimed method of identifying an antibody were using the same antigen to produced antibody therefore, the reference antibody would inherently bind to receptor having WSX motif within SEQ ID NO2 with same K_d and have the same IC50 in a KIRA ELISA.

Claims 10-12 are included because the reference antibodies that specifically binding to extracellular domain of ObR would inherently have biological characteristics of an antibodies of the instant claims.

The reference teachings anticipate the claimed invention.

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskyi, Ph.D.
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Technology Center 1600
May 5, 2003

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